LITE DEPALMA GREENBERG & RIVAS, LLC
ATTORNEYS AT LAW
TWO GATEWAY CENTER
12TH FLOOR
NEWARK, NEW JERSEY 07102-5003
(973) 623-3000
TELEPHONE
(973) 623-0858
FACSIMILE

March 22, 2007

VIA HAND DELIVERY

Honorable Harold A. Ackerman, U.S.D.J.
United States District Court
District of New Jersey
United States Post Office & U.S. Courthouse
Room 305
Newark, New Jersey 07101-0999

Re: Novartis Corporation, et al. v. Teva Pharmaceuticals USA, Inc.
Civil Action No. 04-4473 (HAA)

Dear Judge Ackerman:

This firm, together with Goodwin Procter LLP, represents defendants Teva Pharmaceuticals USA, Inc., et al. ("Teva") in the above-captioned case. We write in response to David DeLorenzi's letter dated March 21, 2007 on behalf of Novartis.

The Hatch-Waxman Act does not require that Teva further delay any launch of its generic benazepril/amlodipine product following the receipt of final approval. To the contrary, the statute explicitly requires the FDA to postpone final approval of an ANDA for only 30 months. As Novartis acknowledges in its letter, that 30-month stay of approval is already expired in this case.

Moreover, Novartis' letter mischaracterizes the prior exchange between the parties concerning Novartis's so-called "emergency" scheduling issue. On Monday, March 19, Novartis first raised the question of whether Teva would agree to provide notice to Novartis before the launch of a generic benazepril/amlodipine product. (Letter from Jeffrey Oelke to Daryl Wiesen attached as Exhibit A). Novartis requested a response by the close of business the next day. On Tuesday, March 20, Teva responded by stating that, in order to avoid burdening the Court with a motion for a temporary restraining order, Teva would agree to a schedule for briefing a motion for preliminary injunction. Teva further proposed a schedule and offered to agree not to launch a generic product until the earlier of a ruling on that motion or June 1, 2007. (Letter from Daryl Wiesen to Jeffrey Oelke attached as Exhibit B). Mr. Wiesen further phoned Mr. Oelke and indicated Teva's willingness to discuss this issue.

This offer should have resolved Novartis' request for advance notice of a launch. Novartis claims that the only reason it needs advance notice is to have sufficient time to prepare for a preliminary injunction hearing. But Teva proposed such a schedule in its March 20 letter. Rather than respond to Teva, Novartis requested the "intervention of Your Honor on an emergency basis."

While Novartis asserts that it "had no expectation that Teva would launch 'at risk' at this time," such a claim is not credible. Teva, the world's largest generic pharmaceutical manufacturer, has launched generic products "at risk." For example, Teva launched fexofenadine while litigation was ongoing in this Court and, just last December, launched bupropion while litigation was ongoing in the Eastern District of Pennsylvania. In those cases, as in others, Teva launched without providing any notice, as it is permitted to do by statute. That Teva has agreed, in different factual circumstances, to provide advance notice to allow resolution of a preliminary injunction is irrelevant here.

Novartis created any "emergency" by its own delay in raising this issue. Novartis has been aware since at least July 2006, when Teva received tentative approval for its product, that Teva would likely be able to launch on March 26, 2007. Despite that fact, Novartis did not raise any question concerning a launch until March 19, 2007. If Novartis had raised this question earlier, no "emergency" would exist.

Nonetheless, Teva agrees that a conference with the Court to address the scheduling of a preliminary injunction motion is appropriate. Teva therefore requests that the Court hold such a conference in-person at the Court's earliest convenience.

Respectfully,

Michael E. Patunas

MEP:emp
Enclosures
cc: David DeLorenzi, Esq. (via facsimile)
Jeffrey Oelke, Esq. (via facsimile)
Ira J. Levy, Esq. (via facsimile)
Daryl L. Wiesen, Esq. (via facsimile)

WHITE & CASE

White & Case LLP
1155 Avenue of the Americas
New York, New York 10036-2787

Tel + 1 212 819 8200
Fax + 1 212 354 8113
www.whitecase.com

Direct Dial + 212-819-8936 joelke@whitecase.com

March 19, 2007

VIA FACSIMILE & FEDERAL EXPRESS

Daryl L. Wiesen, Esq.
Goodwin Procter
Exchange Place
53 State Street
Boston, MA 02109

Re: Novartis Corp et al. v. Teva Pharm. USA, Inc. (C.A. No 04:4473 (HAA) (ES))

Dear Daryl:

We are in receipt of Michael Patunas's letter to the Court requesting that the April 4, 2007 telephone status conference with Magistrate Judge Salas be moved to April 5, 2007. Please notify us as soon as you become aware of a time for the conference on April 5.

I also write concerning a topic I earlier raised with Ira Levy. If Teva intends to launch its generic version of Lotrel prior to a trial in this action, we request that Teva give both Novartis and the Court adequate notice in advance of such a launch so that a schedule for briefing a preliminary injunction motion can be worked out. We are preparing a letter to the Court on this issue and therefore request a response by close of business tomorrow, March 20, 2007. If you wish to discuss, please feel free to contact us.

Sincerely,

Jeffrey J. Oelke

JJO:lr

cc: Michael Patunas, Esq.
David DeLorenzi, Esq.

GOODWIN | PROCTER

Daryl L. Wiesen
617.570.1396
goodwinprocter.com

Goodwin Procter LLP
Counsellors at Law
Exchange Place
Boston, MA 02109
T: 617.570.1000
F: 617.523.1231

March 20, 2007

By Facsimile

Jeffrey Oelke
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036

Re: Novartis Corporation v. Teva Pharmaceuticals USA, Inc.
Civil Action No.: 04-4473 (HAA)

Dear Jeff:

I write in response to your letter of March 19, 2007.

Your insistence that Teva respond within one day is unreasonable in light of the long delay by Novartis in raising the question of a launch by Teva prior to trial. Novartis filed suit in this matter on September 17, 2004. The thirty-month stay on the launch of Teva's product based upon the initiation of the lawsuit has already expired. Furthermore, Novartis is aware that Teva filed a Paragraph III certification concerning U.S. Patent No. 4,879,303; according to the Orange Book, that patent will expire on March 25, 2007. Novartis has therefore been aware for months, if not years, that the market limiting date for the launch of Teva's product is March 25, 2007. Despite that, Novartis waited until less than a week before the market limiting date to write concerning this issue. When I spoke to your partner Leslie Morioka on Friday concerning the scheduling of the status conference with Magistrate Judge Salas, she did not even mention this question.

Teva will not agree to provide advance notice of a launch of a generic benazepril/amlodipine product to Novartis. However, Teva is willing to discuss an expedited schedule for briefing a preliminary injunction motion, if Novartis intends to file such a motion. Any time pressure to resolve a preliminary injunction is of Novartis's own making. If you had raised this question substantially before March 25, 2007, there would have been more time to address it.

GOODWIN | PROCTER

Teva will agree to the following expedited schedule for resolution of a preliminary injunction motion (with the Court's permission):

Motion and supporting papers due:	March 26, 2007
Opposition and supporting papers due:	April 9, 2007
Reply:	April 16, 2007
Sur-Reply:	April 23, 2007
Hearing:	During the week of May 7, 2007

In order to avoid burdening the Court with a motion for a temporary restraining order, Teva is further willing to agree not to launch its generic benazepril/amlodipine product until the earlier of the decision by the Court on the motion for preliminary injunction or June 1, 2007, if the Court adopts this schedule (or a substantially similar schedule). Novartis must further agree not to launch or to take any steps to launch a so-called "authorized generic" during this time period.

I am available to discuss this matter. Please let me know if you would like to talk.

Sincerely,

Daryl L. Wiesen

cc: Ira J. Levy
Michael Patunas